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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/374,565 08/13/99 STOUGHTON

R 9301-058

020583
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HM22/1023

EXAMINER

SIU.S

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

10/23/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/374,565	Applicant(s) STOUGHTON ET AL.	
	Examiner Stephen C Siu	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-45 and 48-87 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 41-45 and 48-87 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- | | |
|--|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 16) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The List of References Cited By Applicant contains US Patent applications and Provisional applications, specifically, 09/031,216; 09/099,722; 60/084,742; 60/090,004; 60/090,046; and 60/092,512. References to these applications have been lined out due to printing restrictions. Provisional applications 60/084,742; 60/090,004; 60/090,046; and 60/092,512 according to common practice, are nevertheless considered. US Patent applications 09/031,216 and 09/099,722 are allowed files and were not available for review at the time of examination. Therefore, they could not be considered.

Claim Objections

Claim 50 is objected to because of the following informalities: the word "selected" is misspelled (last word in the claim). Appropriate correction is required.

Claim 61 is objected to because of the following informalities: the word "transcript" is misspelled (line 4 of the claim). Appropriate correction is required.

Claim 81 is objected to because of the following informalities: the word "first" is misspelled (line 4, section (a)(i)). Appropriate correction is required.

Claim 87 is objected to because of the following informalities: the word "cellular" is misspelled (line 2 of step (b)). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41-45 and 48-87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 41, 80-83, 86, and 87 recite “comprising measurements of (a plurality of) cellular constituents” or “measuring cellular constituents” which is confusing because it is not clear what is being measured or the nature of the measurements being performed. For example, it may indicate quantitative (i.e. levels of cellular constituents) measurements or qualitative measurements.

Claims 41, 44, 80-82, 84, 85, and 87 recite “objective function” which is confusing because it is not clear what is meant by “objective function” in this context or how it differs from “a function”.

Claim 42 recites “said drug response measurements” which lacks antecedent basis. The dependent claims recites “measurements of cellular constituents”.

Claim 49 recites “determining a theoretical minimum values” which is confusing because it is not clear if there is one or multiple values with the simultaneous use of “a” and the plural form of “value”.

Claim 69 recites “a method comprising... transfection of genes expression the one or more...” which is confusing because it is not clear what is meant with the use of the word “expression” in this context.

Claims 76-79 recite “The method of claim (XX)” which is confusing because the claims on which claims 76-79 depend are drawn to a computer system and not a method.

Claim 80 recites "a more pathway specific drug...from..." which is confusing because it is not clear with what the drug is more pathway specific with the use of the word "from".

Conclusion

No claims allowed, The term "biological pathway" as recited in the instant claims is interpreted to mean cellular constituents with similar patterns of mutual influences after exposure to a perturbing condition (e.g. exposure to various drugs or from various genetic manipulations), the collection(s) of cellular constituents varying in a correlated fashion with a network of mutual influences linking the collection of cellular constituents into a "biological pathway" being inferred from a similar pattern of variations in different conditions, the collection of such cellular constituents being a "biological pathway" as stated in the specification, page 24, 1-7 and page 23, lines 20-37. No prior art was found that anticipated the present invention or rendered the present invention obvious to one of ordinary skill in the art, however, the instant claims are rejected for other reasons. The closest prior art, Ecker (J. Pharm. Pharmacol. 49:305-309, 1997, PTO-1449 reference CT) teaches providing a drug response in a cell type by measuring a plurality of cellular constituents involved in the cellular reduction of MTT at a plurality of exposure levels, representing a model drug response and performing a scaling transformation and determining the best scaling transformation to yield the biological pathways involved in the drug action. However, the method of Ecker does not does not identify the "biological pathways" involved in drug action, the term "biological pathways"

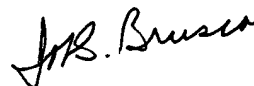
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as being defined above. Thus, it is not believed that Ecker anticipates the present invention or renders the present invention obvious to one of ordinary skill in the art.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stephen Siu, whose telephone number is (703) 308-7522. The Examiner can normally be reached from 7:00 a.m. to 3:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028. Papers related to this application may be submitted to Art Unit 1631 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 308-0294. Please call the Examiner at (703) 308-7522 before the transmission to expedite delivery of the fax. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stephen Siu



JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER